

**REMARKS**

The Office Action mailed June 29, 2005, has been received and reviewed. Claims 2-27 are pending in the application. Claims 2-27 stand rejected. Claims 2, 3, 5-9, 11, 12, 14, 18-24, 26, and 27 are amended as previously set forth. Claims 1 and 28-35 have been canceled. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

**Interview Summary**

Applicants extend their thanks to the Examiner for the interview conducted on September 27, 2005 at the Patent Office. In attendance were the Examiner, Bob van Gemen, Allen Turner, and M.P.W. Einerhand. The differences between the art and the claims were discussed. Also discussed were non-limiting amendments to overcome the novelty rejection and arguments to be made to overcome the obviousness rejection.

**Restriction Requirement**

Applicants affirm the election of Group I, claims 1-27.

**Claim Objections**

Claim 27 stands object to for allegedly lacking a period at the end of the sentence. Applicants have amended Claim 27 by adding a period, thereby mooting the rejection.

**Rejections under 35 USC §112, 2<sup>nd</sup> ¶**

Claim 20 stands rejected as allegedly being indefinite for use of the term "precious." Applicants have canceled the term "precious," thereby broadening the scope of the claim.

**Rejections under 35 USC §102(b)**

Claims 1, 2, 5, 7, 10, 14-18, 20-24, and 26 stand rejected as being anticipated by Yourno (*Jour. Of Clin. Micro.*, 1992, 30(11): 2887-2892)(hereinafter referred to as the "1992 Yourno article"). Applicants have canceled claim 1 and amended claim 2 to incorporate the elements of claim 3. Further, the dependency of the remaining claims was amended to depend from claim 2. As claim 3 was not rejected as anticipated, Applicants respectfully request reconsideration.

**Rejections under 35 USC §103(a)**

Claims 3, 4, 6, 8, 9, 11-13, 19, 25, and 27 stand rejected as allegedly being obvious over the 1992 Yourno article as applied to the §102 rejection and in further view of US 5,482,834 (hereinafter referred to as the '834 patent) and Higuchi *et al.* (*Bio/Technology*, 1993, 11:1026-

1030)(hereinafter referred to as the "Higuchi article"). Applicants respectfully request reconsideration of the rejection in light of this response and the differences between the Yourno article, the '834 patent, and the Higuchi article.

The Examiner begins by asserting that Applicants' claims 3, 4, 6, 8, 9, 11-13, 19, 25, and 27 are drawn to limitations wherein two different samples are adsorbed to the carrier wherein 100 or 250 microliters of a sample are applied to a solid carrier. Applicants have amended claim 2 to add the element that the sample size is at least 100 $\mu$ l. Accordingly, Applicants claimed invention now requires an element of at least 100 $\mu$ l sample.

The Examiner asserts that Higuchi discloses a real-time monitoring of DNA amplification reactions and thatt would have been obvious to use real-time PCR with Yourno's method. The Examiner further asserts that the '834 patent discloses the use of a chaotropic salt solution along with nucleic acid probes to improve hybridization of probes with their targets. The Examiner then asserts that if blood is taken from a patient or test subject according to the teachings of the Yourno article, the '834 patent, and the Higuchi article, (about 50 $\mu$ l per sample) at separate times, but is spotted at the same time on different places on the filter paper, the total amount of blood would be expected to reach 100 or 250 microliters, as is claimed. However, Applicants respectfully request reconsideration in light of the plain meaning of the claimed invention of claims 2, 3, 5-9, 11, 12, 14, 18-24, 26, and 27, as amended.

Applicants claim 2, as amended is "[a] process for detecting and quantifying a nucleic acid of interest in at least one sample, the process comprising:

administering **at least 100 $\mu$ l** of the at least one sample to a solid carrier capable of absorbing the at least one sample;... ." (emphasis added).

None of the cited references disclose administering **at least 100 $\mu$ l** of the at least one sample. In fact, even the Examiner admits that individual sample sizes disclosed are only 50 $\mu$ l. Accordingly, the element of "at least 100 $\mu$ l" is not disclosed by the cited art. Therefore, the combination of the cited art is not Applicants' invention and the Examiner has not established a *prima facie* case of obviousness.

Paragraphs 12-16 of Applicants' specification illustrate some of the non-obvious aspects of using a sample size of at least 100 $\mu$ l. Embodiments of the claims 2, 3, 5-9, 11, 12, 14, 18-24, 26,

and 27, as amended, allow detection of low titers of nucleic acid(s) of interest even with a high sample volume without any methanol pretreatment.

Paragraph 12 illustrates a major drawback in current detection methods is that only nucleic acid with a concentration above a certain threshold value can be detected. This means that infected individuals with a low load of pathogenic nucleic acid are not diagnosed as being infected and, hence, do not get treatment at an appropriate early timepoint. The embodiments of claims 2, 3, 5-9, 11, 12, 14, 18-24, 26, and 27, as amended, overcome this problem in the art.

Surprisingly, with the methods of claims 2, 3, 5-9, 11, 12, 14, 18-24, 26, and 27, as amended, of the invention high amounts of sample can be stored on a dried solid carrier and subsequently analyzed. With a method of the invention it is now possible to analyze large samples for the presence of a nucleic acid of interest. Hence, low concentrations of a nucleic acid of interest in a sample can now be detected. Accordingly, there are considerable indicia of non-obviousness present in the claimed invention of claims 2, 3, 5-9, 11, 12, 14, 18-24, 26, and 27, as amended. Therefore, Applicants respectfully request removal of the rejection.

### **CONCLUSION**

Entry of the foregoing amendments and reconsideration of the rejections is respectfully requested. The Examiner is invited to contact Applicants' attorney for any assistance.

Respectfully submitted,



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